



**INTEGRATIVE THERAPEUTICS INC.**  
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9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 • F: 503.582.0467

**ENZYMATIC THERAPY®  
&  
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 • F: 888.570.6460 (Enzymatic)

P: 920.469.9099 • F: 920.469.4418 (Phyto)

## ENZYMATIC THERAPY

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*What **Better** feels like.™*

December 22, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

DEC 23 2005


RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	End brain fog.*	Acetyl-L-Carnitine HCl, L-Glutamine, Lecithin, Phosphatidylcholine, Phosphatidylethanolamine, Phosphatidylinositol, L-Pyroglutamic acid, L-Tyrosine, Eleuthero Root (Eleutherococcus senticosus) extract, Ashwagandha Root (withania somnifera) Extract, Choline (as choline bitartrate), Bilberry Fruit (Vaccinium myrtillus) Extract, DMAE (dimethylaminoethanol bitartrate), Phosphatidylserine (soy lecithin source), Ginkgo Biloba Leaf Extract, Docosahexaenoic Acid

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

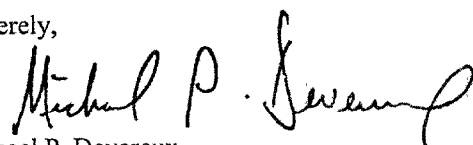
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/22/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Operations Officer

975 0162

LET 17143



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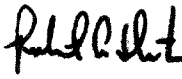
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Supports healthy memory and enhances mental focus and concentration.*	Acetyl-L-Carnitine HCl, L-Glutamine, Lecithin, Phosphatidylcholine, Phosphatidylethanolamine, Phosphatidylinositol, L-Pyroglutamic acid, L-Tyrosine, Eleuthero Root (Eleutherococcus senticosus) extract, Ashwagandha Root (withania somnifera) Extract, Choline (as choline bitartrate), Bilberry Fruit (Vaccinium myrtillus) Extract, DMAE (dimethylaminoethanol bitartrate), Phosphatidylserine (soy lecithin source), Ginkgo Biloba Leaf Extract, Docosahexaenoic Acid

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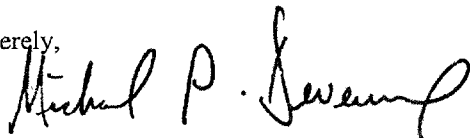
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Along with coenzyme Q10, L-carnitine is a key factor in metabolism, supporting the production of cellular energy.*	Acetyl-L-Carnitine HCl

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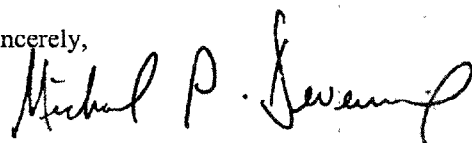
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Supplemental acetyl L-carnitine can serve as a buffer against oxidative stress.*	Acetyl-L-Carnitine HCl

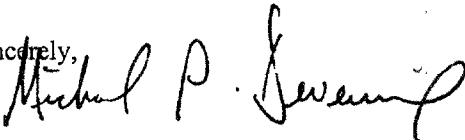
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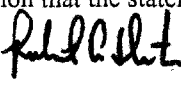
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Phosphatidylcholine is a major constituent of cellular membranes and a rich source of polyunsaturated fatty acids. It supports cell membrane flexibility and integrity.*	Lecithin

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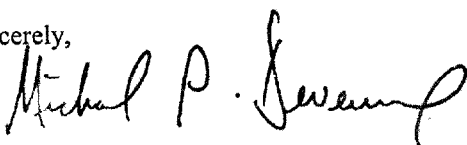
By:   
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Title: Senior Vice President of Scientific Affairs

Date: 12/22/05

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Chief Operations Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Phosphatidylcholine is a source of choline, a precursor in the synthesis of neurotransmitter acetylcholine. Supplementation can support healthy neurological and cognitive function.*	Lecithin

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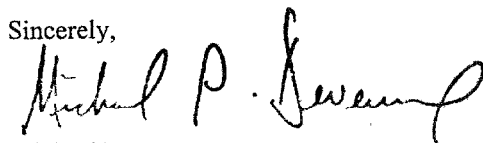
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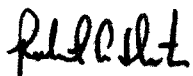
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Pyroglutamic acid has been clinically shown to improve symptoms of mild memory loss associated with aging.* It works by supporting healthy brain vessel tone and circulation in the brain.	L-Pyroglutamic acid,

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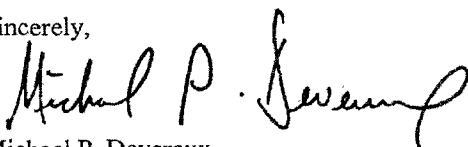
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Supplementation with L-Tyrosine can improve mood.*	L-Tyrosine

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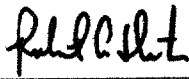
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Ashwagandha supports red blood cell formation and stress resistance.*	Ashwagandha Root (withania somnifera) Extract

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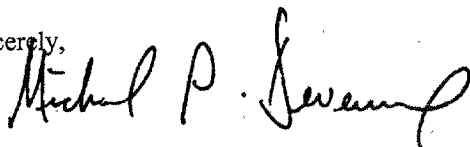
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Brain Fog Lifter™*	In clinical study, physical endurance was doubled in participants given extracts of withania somnifera. * The withanolides, compounds found in ashwagandha, appear to support the body's natural ability to combat stress.*	Ashwagandha Root (withania somnifera) Extract

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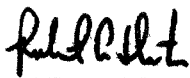
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Brain Fog Lifter™*	Choline supports the healthy production of acetylcholine, a major neurotransmitter that facilitates the transmission of impulses between neurons.*	Choline (as choline bitartrate)

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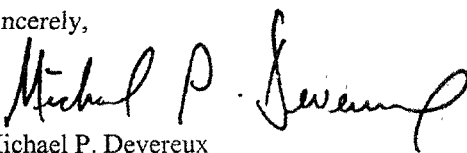
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Chief Operations Officer

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December 23, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Bilberries contain powerful antioxidants that protect neuronal cells from oxidative damage.*	Bilberry Fruit ( <i>Vaccinium myrtillus</i> ) Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Operations Officer

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Brain Fog Lifter™*	Choline-precursor DMAE promotes healthy cognitive function.*	DMAE (dimethylaminoethanol bitartrate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

12/23/05

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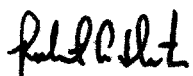
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	DMAE has been clinically studied to support focus and concentration.*	DMAE (dimethylaminoethanol bitartrate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

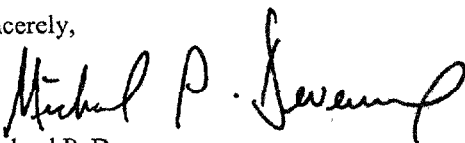
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/23/05

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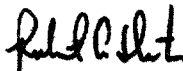
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	In combination with vitamins and minerals, DMAE can promote feelings of well-being.*	DMAE (dimethylaminoethanol bitartrate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

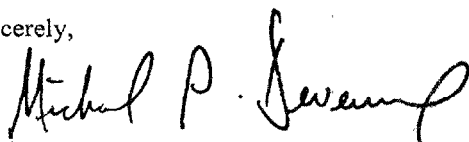
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/23/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Phosphatidylserine supports neurological health at a cellular level.*	Phosphatidylserine (soy lecithin source)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

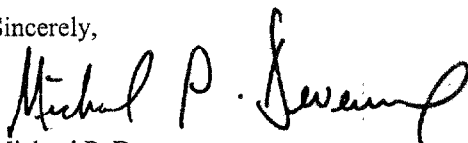
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/23/05

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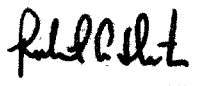
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Supplementation enhances cognition, concentration and mental function.*	Phosphatidylserine (soy lecithin source)

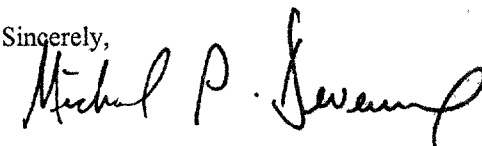
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By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/23/05

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RE: Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Phosphatidylserine is also involved in the production of neurotransmitters.*	Phosphatidylserine (soy lecithin source)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

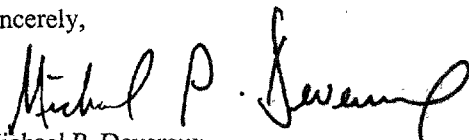
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/23/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Ginkgo biloba has long been used to support improved short-term memory and mild memory problems associated with aging.*	Ginkgo Biloba Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

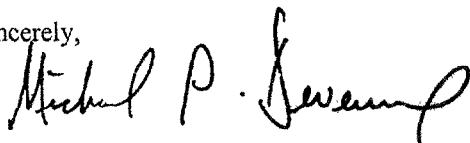
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Title: Senior Vice President of Scientific Affairs

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	More than 400 studies document its beneficial effects for cognitive function.*	Ginkgo Biloba Leaf Extract

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By: Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/23/05

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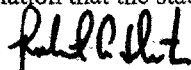
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	Ginkgo works by promoting healthy circulation and increasing blood and oxygen flow in the brain.*	Ginkgo Biloba Leaf Extract

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By: \_\_\_\_\_

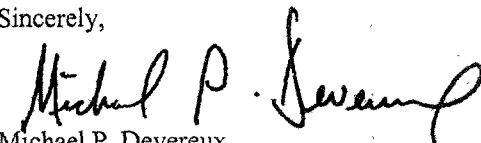
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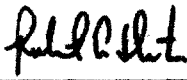
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	A placebo controlled, multi-dose, double-blind, balanced, crossover study examined the effect of ginkgo on four cognitive measurements in healthy volunteers. Speed of attention, accuracy of attention, speed of memory, and quality of memory were assessed prior to dosing and at established times thereafter. Compared with placebo, ginkgo provided support of several cognitive measures.* The most striking of these was support of the "speed of attention" score.*	Ginkgo Biloba Leaf Extract

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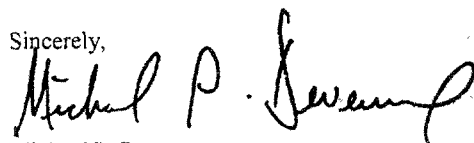
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P: 920.469.9099 • F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY INCORPORATED

What **Better** feels like.™

December 23, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Brain Fog Lifter™*	DHA is essential for the development and maintenance of neural structures in the brain.*	Docosahexaenoic Acid

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster  
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Michael P. Devereux  
Chief Operations Officer

### INTEGRATIVE THERAPEUTICS INC.™

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### ENZYMATIC THERAPY™

&  
PHYTOPHARMICA™

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P: 920.469.9099 • F: 920.469.4418 (Phyto)